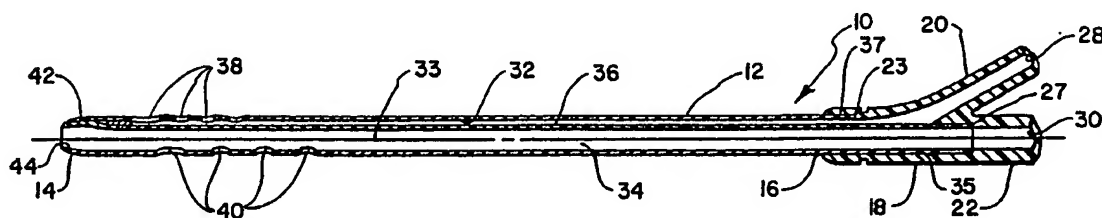




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(54) Title: DUAL-LUMEN CATHETER APPARATUS AND METHOD**(57) Abstract**

A dual-lumen catheter apparatus and method. The apparatus has an elongated catheter body (12) adapted for insertion into a vein or a fluid-containing body cavity of a patient such as the right atrium of a heart. The catheter body (12) has a septum (36) that runs longitudinally through the interior of the catheter body (12) so as to divide the interior of the catheter into a first and a second lumen (32, 34). The septum (36) is offset from the longitudinal center axis of the catheter so that the cross-sectional area of the two lumens (32, 34) are of different sizes. The first lumen (34) has a cross-sectional size that is relatively large so that a sufficient volumetric flow rate of blood that is to be oxygenated is able to flow by means of gravity drainage through the first lumen (34) whereas the second lumen (32) is smaller but is still sufficiently large so that an essentially equal volumetric flow rate of blood that has been oxygenated can be returned under pressure through the second lumen (32).

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1 DUAL-LUMEN CATHETER APPARATUS AND METHOD

BACKGROUND1. The Field of the Invention

5 The present invention relates to catheters and, more particularly, the present invention is related to a dual-lumen catheter for use in extracorporeal oxygenation or other similar applications.

10 2. The Present State of the Art

In response to the need of patients with respiratory distress who fail to respond to conventional ventilatory management, many extracorporeal life support (ECLS) procedures and techniques have been developed to provide pulmonary and/or cardiac support for such patients. 15 Extracorporeal membrane oxygenation (ECMO) is a life support technique which employs a cardiopulmonary bypass with a heart-lung machine to provide gas exchange, and to permit lungs to rest from damaging pressure and oxygen associated with conventional ventilation therapy. ECMO is 20 often associated with neonatal respiratory dysfunction.

At the present time, two ECMO procedures are well known: venoarterial (VA) ECMO and venovenous (VV) ECMO. VA ECMO entails circulating the patient's blood through an extracorporeal system which pumps, oxygenates, and warms 25 the blood. In order to withdraw the blood from the patient the right internal jugular vein is cannulated for venous drainage. The right common carotid artery is also cannulated for perfusion of the machine-oxygenated blood.

30 VV ECMO also entails circulating the patient's blood through an extracorporeal system which pumps, oxygenates, and warms the blood. The distinction lies in the drainage and perfusion of blood. In VV ECMO, blood drainage is also accomplished by cannulation of the right jugular. However, 35 perfusion takes place in a vein rather than an artery. In VA ECMO, the perfusion of oxygenated blood is into the common carotid artery by employing a cannula placed in the

1 common carotid artery at the level of the aortic arch. In
VV ECMO, the perfusion of the oxygenated blood is into the
femoral vein by employing a cannula secured in the femoral
vein. This spares the common carotid artery.

5 In both VA and VV ECMO, the cannulation of the right
jugular for drainage requires insertion of a catheter down
the right jugular, into the superior vena cava, and into
the right atrium of the heart. It is from the right atrium
that blood drainage typically occurs in ECMO. Withdrawal
10 of the blood from the right atrium is typically by gravity
flow, and the blood enters an extracorporeal circuit which
oxygenates and warms the blood to suitable levels. The
extracorporeal circuit then pumps the oxygenated blood back
into the patient for circulation in the body.

15 One drawback of both VA ECMO and VV ECMO is the
necessary ligation of two primary veins and/or arteries.
It is generally accepted that ligation poses the threat of
future neurologic complications. Attempts to solve this
problem have led to procedures involving a single ligation
20 and cannulation, which use a tidal flow method (TF). In
other words, the action of withdrawal and perfusion are
mutually exclusive with respect to time through the same
passage in a single cannula. While TF ECMO reduces the
number of ligations from two to one, it does not permit
25 continuous and simultaneous withdrawal and perfusion of
blood, and also results in recirculation of venous blood
with oxygenated blood, since both withdrawal and return
occur at the same site. Accordingly, it would be an
important advance in the art to provide an apparatus and
30 method which would permit the number of ligations necessary
to provide ECLS to be reduced to one rather than two
without being limited to a tidal flow method with its
attendant disadvantages.

BRIEF SUMMARY OF THE INVENTION

35 An apparatus which comprises an elongated catheter
body that is adapted for insertion into a vein or fluid-
containing body cavity of a patient, such as the right

1 atrium of a heart. The catheter body comprises a septum
that runs longitudinally through the interior of the
catheter body so as to divide the interior of the catheter
into a first and a second lumen. The septum is offset from
5 the longitudinal center axis of the catheter so that the
cross-sectional area of the two lumens are of different
sizes. The first lumen has a cross section size which is
relatively large so that a sufficient volumetric flow rate
of blood that is to be oxygenated is able to flow by means
10 of gravity drainage through the first lumen. The first
lumen terminates in an opening at the distal end of the
catheter and additional entry of blood into the first lumen
occurs by means of a first plurality of longitudinally
spaced openings formed through the wall of the catheter
15 body.

The septum that runs through the catheter body is
sealed near the distal end of the catheter body so that the
second lumen terminates at a point that is slightly behind
the distal end of the catheter. Return of oxygenated blood
20 under pressure occurs through the second lumen by means of
a second plurality of holes that are longitudinally spaced
and are formed through the catheter body diametrically
opposite to the first plurality of openings. In this
manner the withdrawal of blood that is to be oxygenated and
25 the return of oxygenated blood is separated by the maximum
distance so as to advantageously minimize the recirculation
of venous blood with oxygenated blood. The cross-sectional
area of the second lumen is sized so that at the selected
pressure at which the oxygenated blood is returned, the
30 volumetric flow rate of the blood through the second lumen
will be essentially equal to the volumetric flow rate which
occurs by means of gravity drainage through the first
lumen.

35 Significantly, by means of the dual lumen catheter
apparatus of the invention, only a single ligation is
necessary in order to accomplish simultaneous withdrawal of
venous blood and return of oxygenated blood.

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BRIEF DESCRIPTION OF THE DRAWINGS

In order to more fully understand the manner in which the above-recited advantages and objects of the invention are obtained, a more particular description of the invention will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope, the presently preferred embodiment and the presently understood best mode of the invention will be described with additional detail through use of the accompanying drawings in which:

Figure 1 is a perspective view of one presently preferred embodiment of the dual-lumen catheter of the present invention;

Figure 2 is a longitudinal cross-section of the embodiment of Figure 1 taken along lines 2-2, and more particularly illustrating the internal dual-lumen structure of the catheter;

Figure 3 is a cross-section of the embodiment of Figure 1 taken along lines 3-3, and illustrating the eccentric configuration of the two lumens.

Figure 4 is a perspective view of the position of the dual-lumen catheter in position in the right atrium of the heart with venous drainage occurring in the right atrium chamber and perfusion occurring by directing the flow of infusion in the direction of the tricuspid valve at the opening into the right ventricle; and

Figure 5 is an enlarged cross-sectional view of the distal end of the dual-lumen catheter in position in the right atrium of the heart, and schematically illustrating the manner in which venous blood is withdrawn through a first lumen of the catheter while oxygenated blood is returned under pressure through the second lumen of the catheter in a manner which minimizes recirculation of the venous blood with the oxygenated blood.

1

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTSA. General Design Considerations

Important objectives of any ECMO procedure include
5 maintaining adequate venous drainage, oxygenation, and
perfusion of the blood to compensate for any recirculation
which might occur. Recirculation is a common occurrence
when a fluid withdrawal/perfusion system such as ECMO takes
place in a spherical structure such as the right atrium.
10 Preferably, however, the venous, or oxygen depleted blood
is not recirculated through the body with oxygenated blood.
Therefore, a single catheter system must be so configured
such that venous blood is effectively withdrawn from the
patient without permitting impermissibly large quantities
15 of oxygen depleted blood to reenter the circulatory system
of the patient for another pass through the body. As a
result, the withdrawal and perfusion functions of the
catheter or cannula must be designed so that clinically
permissible levels of recirculation are not exceeded.

20 A practical limitation of the size of any ECMO
catheter is the size of the artery or vein in which the
catheter is placed. For example, in a newborn a number 14
fr catheter is the largest catheter that will pass through
the newborn's jugular enroute to the right atrium for
25 venous drainage. The jugular of a larger child,
adolescent, or adult would, naturally, tolerate a
proportionately larger catheter.

A critical aspect of ECMO techniques is the requisite
quantity of blood flow from and to the patient. The
30 configuration of the lumen withdrawing blood and the lumen
perfusing blood must be of sufficient size, configuration
and location so as to contribute to effective ECMO. For
example, in order to provide adequate venous drainage, and
in order to do so employing gravity suction (approximately
35 100-120 cm of syphon) while attaining a volumetric flow
rate sufficient for oxygenation of approximately 500
cc/min. for a newborn and up to 5 l/min. for an adult, the

1 drainage lumen must be of a relatively large size to
provide such volumetric flow rates by means of gravity
drainage.

Similarly, the lumen employed to perfuse the machine-
5 oxygenated blood must also permit a volumetric flow rate
compatible with the required ECMO blood flow levels and
with the care necessary to avoid damaging the blood.
Because blood is reinfused under pressure from the pump of
the ECMO circuit, the size and configuration of the
10 perfusion lumen may be smaller than the gravity drainage
lumen. However, there are practical limitations to the
pressure at which blood may be reinfused.

In order to avoid traumatizing the blood, the
reinfusion pressure must be kept in a preferred range. For
15 example, if reinfusion pressure exceeds 300-400 mm Hg, the
blood becomes traumatized and breaks down. In order to
prevent traumatization of the blood, it is desired to
maintain the pressure of reinfusion at approximately 250 mm
Hg. In addition, a certain volumetric flow rate of
20 perfusion is needed, typically equal to the volumetric rate
of withdrawal.

While gravity venous drainage must attain a certain
volumetric flow rate, thus requiring an appropriately
configured drainage lumen, and while reinfusion takes place
25 under pressure and must return to the body the requisite
volumetric flow rate, thus requiring a certain size or
configuration of the perfusion lumen, the combined cross-
sectional area of the two lumens may not exceed the
practical limitation of the size of the vein or artery in
30 which the catheter is placed or through which the catheter
or cannula must pass.

The distal end of the catheter must be configured so
as not to traumatize the vessel walls into which the
catheter is placed or through which it must pass. In this
35 respect, the tip of the catheter is generally tapered and
rounded, avoiding sharp or abrupt edges. If the tip of the
catheter has an opening, the opening must not be so small

1 that surface tension around the opening inhibits the
required flow capacity of the catheter system. Therefore,
it is necessary to configure the distal end of the catheter
so that the flow of blood into the distal end of the
5 catheter is not inhibited by surface tension.

Another desired function of the catheter apparatus is
prevention of oxygenated blood from merely staying in the
ECMO circuit cycle. The catheter should, to the extent
possible, maximize the circulation of oxygenated blood and
10 inhibit the oxygenated blood from reentering the
extracorporeal circuit before it has passed through the
patient. Therefore, the distal end of the catheter must be
configured such that the function of withdrawing blood and
perfusing blood, while occurring in relatively close
15 proximity nonetheless are sufficiently located and spaced
apart so as to avoid recirculation and reoxygenation of
oxygenated blood. In other words, the configuration of the
distal end of the catheter should permit the withdrawal of
venous blood, and simultaneously control the direction
20 and/or flow of perfused, oxygenated blood so that
clinically permissible levels of recirculation are not
exceeded and sufficient quantities of oxygenated blood are
introduced into the patient for circulation through the
patient's body.

25

B. Description of the Embodiment of Figures 1-5

The following detailed description of the presently
preferred embodiment of the invention as illustrated, for
example, in Figures 1-5 illustrates how the general design
30 considerations of the invention, as described above, may be
implemented. In the drawing figures like parts have been
designated with like numerals throughout.

Reference is first made to Figure 1 which illustrates
a perspective view of the presently preferred embodiment.
35 The catheter apparatus is generally designated at 10 and is
comprised of an elongated catheter body 12 which terminates
at its distal end 14 in a rounded tip and which is attached

1 at its proximal end 16 to a Y connector 18. Distal end 14
of the elongated catheter body 12 is rounded and slightly
tapered, as shown best in Figure 2, so as to minimize the
possibility of damaging delicate vessel walls or tissue
5 walls as the catheter is inserted into the right atrium of
the heart, as hereinafter more fully described in
connection with Figures 4 and 5.

With continued reference to Figures 1 and 2 taken
together, it will be seen that the elongated catheter body
10 12 is comprised of a septum means for forming a first and
a second lumen through the interior of the catheter body.
In the illustrated embodiment, the septum means for forming
the first and second lumens is illustrated as a septum 36
(see Figure 2) which runs lengthwise through the catheter
15 body and which is offset from the longitudinal center axis
33 of the catheter body so as to define a first lumen 34
and a second, smaller lumen 32. As shown best in Figure 3,
the first lumen 34 is substantially larger in its cross-
sectional area than the second lumen 32. The cross-
20 sectional area of the first lumen 34 is sized so as to
permit a sufficient volumetric flow rate for purposes of
oxygenation of blood as the blood flows through the first
lumen 34 by means of gravity drainage. The blood is
permitted to enter into the first lumen 34, as shown best
25 in Figure 2, through the opening 44 at the distal end of
the catheter body 12 and also through the longitudinally
spaced openings 40 which are located on one side of the
catheter body 12.

The second, smaller lumen 32 is substantially smaller
30 in its cross-sectional area, as shown in Figure 3, than the
first lumen 34. The second lumen 32 is used for return of
blood after it has been oxygenated. Since the blood is
returned by means of a blood pump the blood returning
through the second lumen 32 is pressurized and accordingly
35 the cross-sectional area of the second lumen 32, although
smaller than the cross-sectional area of the lumen 34 is
nonetheless sized so that the volumetric flow rate of the

1 blood which is returned under pressure is essentially equal
to the volumetric flow rate of the blood which is being
withdrawn by gravity drainage through the first lumen 34.
The blood exists from the second lumen 32 by means of the
5 openings 38 which are provided near the distal end of the
catheter body 12. For purposes to be hereinafter more
fully explained, the openings 38 through which the blood is
returned is positioned on the catheter body 12 diametrically
opposite to the openings 40 so that there is a maximum
10 separation between the return openings 38 and the openings
40 through which blood is withdrawn. As will become more
apparent in connection with Figures 4 and 5, this
arrangement serves to minimize recirculation and helps to
maximize the control and direction of perfusion of the
15 oxygenated blood so that it is not withdrawn back into the
catheter apparatus and recirculated for further
oxygenation.

While the relative sizes of the first and second
lumens 34 and 32 may vary somewhat, ultimately the
20 relationship between the size of the two lumens will be
governed by the overall size of the vessel for which the
catheter apparatus is to be used. For example, as noted
above in the general design considerations, a volumetric
flow rate sufficient for oxygenation for a newborn would
25 typically be approximately 500 cc per minute, and could
range up to 5 liters per minute for an adult. Accordingly,
the drainage lumen or first lumen 34 must be of a
relatively large size to provide the required volumetric
flow rate whereas the second or small return lumen 32 may
30 be smaller since the blood is returned under pressure,
while still achieving an essentially equal volumetric flow
rate to that of the first lumen.

With further reference to Figure 2, it will be seen
that the septum 36 is sealed as indicated at 42 at the
35 distal end of the catheter body so that the second or
return lumen 32 terminates slightly behind the outlet 44 of
the gravity drainage lumen 34. By this means the

1 oxygenated blood is required to be returned through the
openings 38 for purposes of directing the return flow of
the oxygenated blood in a direction which is substantially
displaced and is away from the openings 40 and 44 through
5 which the blood that is to be oxygenated is withdrawn.
This minimizes recirculation of the blood that is already
oxygenated with the blood that is to be oxygenated.

With continued reference to Figures 1 and 2, it will
be seen that the Y connector 18 which is attached at the
10 proximal end of the catheter body is formed with two
branches 20 and 22 which provide separate flow passageways
which in turn connect to the two lumens 32 and 34,
respectively. Thus, as shown in Figure 2 the gravity
drainage lumen 34 is in fluid communication with the
15 passageway 30 provided by branch 22 of the Y connector
whereas the return lumen 32 is in fluid communication with
the flow passageway 28 of branch 20 of the Y connector. As
shown in the longitudinal cross-sectional illustration of
Figure 2, the septum 36 and the lower wall 35 of the
20 catheter body 12 extend into the Y connector 18 a
sufficient distance to abut against a diametrically reduced
shoulder 27. The upper wall 37 of the catheter body 12
similarly abuts against a diametrically reduced shoulder 23
so that a proper orientation with respect to the two lumens
25 can be easily obtained and so that the catheter body 12 can
be quickly inserted into and properly oriented relative to
the two connecting passageways 28 and 30 of the Y
connector.

As shown best in Figure 1, the two branches 20 and 22
30 of the Y connector are in turn connected to tubing 24 and
26 which is joined by other appropriate fittings to the
blood oxygenation circuit (not shown). Accordingly, as
will be appreciated from the foregoing, the Y connector
serves as a means for attaching the catheter body to the
35 tubing of the blood oxygenation circuitry and comprises
means forming a first passageway for connection to tubing
through which blood that is to be oxygenated is withdrawn

1 from the first lumen, and means forming a second passageway
for connection to other tubing through which the oxygenated
blood is returned through the second lumen.

5 An obturator 25 may optionally be used to retard blood
flow through the drainage lumen 34 while the apparatus is
being positioned in the heart, as described below. Once
positioned, the obturator 25 is removed and tubing 26 is
connected to the extracorporeal blood oxygenation circuit.

10 Use of the catheter apparatus 10 in connection with
extracorporeal oxygenation is illustrated in Figures 4 and
5. As shown in Figure 4, the elongated catheter body 12 is
passed through the superior vena cava 50 until the catheter
body 12 passes through the opening of the superior vena
15 cava 50 into the right atrium of the heart, which is
generally designated at 48. Catheter body 12 is positioned
such that the openings 40 through which blood is withdrawn
by means of gravity drainage through the first lumen are
directed in essentially the opposite direction from
20 tricuspid valve 54 which is at the opening of the right
ventricle of the heart.

As schematically illustrated in Figure 5 by the arrows
58, blood enters through the opening 44 at the distal end
of the catheter body and also through the openings 40 and
flows through the first lumen 34 by means of gravity
25 drainage. As further schematically illustrated in Figure
5, once the oxygen-depleted blood has been circulated
through the extracorporeal membrane oxygenation circuitry,
it is then returned under pressure through the return lumen
32. The openings 38 which communicate with the return
30 lumen 32 are positioned essentially opposite to the
openings 40 and are directed at the tricuspid valve 54.
Since the blood that is oxygenated is returned under
pressure, the blood is expelled with some force as
schematically indicated at 60 so as to be directed toward
35 the tricuspid valve 54. This serves to help in minimizing
recirculation, although the pressure at which the blood is

1 returned must be maintained within adequate levels so as
not to traumatize the blood, as noted perviously.

From the foregoing, it will be appreciated that a
substantial advantage of the catheter apparatus of the
5 invention is that by means of a single catheter which
requires only a single ligation both venous drainage and
perfusion of oxygenated blood is accomplished. The
catheter of the present invention also permits placement in
the right atrium in a manner which is consistent with and
10 enhances the natural circulatory flow of blood in the
patient. In other words, as will be appreciated, during
normal circulation of blood oxygenated-depleted blood
enters the right atrium through the opening of the superior
vena cava and the inferior vena cava on its way to the
15 right ventricle for subsequent reoxygenation. The catheter
apparatus of the present invention specifically enhances
and assists this type of normal circulation while doing so
with only a single ligation.

The present invention may be embodied in other
20 specific forms without departing from its spirit or
essential characteristics and accordingly, the described
embodiments are to be considered in all respects only as
illustrative and not restrictive. The scope of the
invention is, therefore, indicated by the appended claims
25 rather than the foregoing description, and all changes
which come within the meaning and range of equivalency of
the claims are to be embraced within their scope.

What is claimed is:

30

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1 1. An extracorporeal oxygenation catheter apparatus
designed for simultaneous withdrawal of blood to be
oxygenated by means of gravity drainage and pressurized
return of blood that has been oxygenated, comprising:

5 an elongated catheter body having a distal end
and a proximal end, and comprising a septum means for
forming a first and a second lumen through the
interior of said catheter body, said first lumen
comprising a cross-sectional area sized so that a
10 sufficient volumetric flow rate for purposes of
oxygenation of said blood will occur in said first
lumen as a result of gravity drainage of blood through
the first lumen, and said second lumen comprising a
cross-sectional area which is smaller in relation to
15 said cross-sectional area of the first lumen but which
is also sized so that a substantially equal volumetric
flow rate of said oxygenated blood is returned under
pressure through said second lumen; and

20 connector means joined to said proximal end for
attaching said catheter body to tubing, said connector
means comprising means forming a first passageway for
connection to tubing through which said blood to be
oxygenated is withdrawn from said first lumen, and
means forming a second passageway for connection to
25 other tubing through which said oxygenated blood is
returned to said second lumen.

30 2. An apparatus as defined in claim 1 wherein said
septum means for forming said first and second lumens
comprises a septum which runs lengthwise through said
catheter body, said septum being offset from the
longitudinal center axis of said catheter body so as to
define said cross-sectional areas.

35 3. An apparatus as defined in claim 2 wherein said
septum is sealed to said catheter body at an interior wall
thereof near said distal end of the catheter body, whereby

1 said second lumen terminates at a point that is
longitudinally displaced from said distal end.

4. An apparatus as defined in claims 1 or 3 wherein
5 said apparatus further comprises a first plurality of
longitudinally spaced openings formed on said catheter body
and through which said blood to be oxygenated enters into
said first lumen, and a second plurality of longitudinally
10 spaced openings formed on said catheter body essentially
diametrically opposite to said first plurality of openings
and through which return of said oxygenated blood from
said second lumen occurs, whereby blood to be oxygenated
enters said catheter body on one side thereof and
15 oxygenated blood is returned from said catheter body at an
essentially opposite side thereof so as to maximize
separation between blood that is withdrawn from oxygenated
blood that is returned.

5. An apparatus as defined in claims 1 or 3 wherein
20 said distal end of said catheter body is tapered, rounded
and comprises an opening which communicates with said first
lumen.

25 6. In improved dual lumen catheter apparatus having
an elongated catheter body with a tapered distal end for
insertion into a vessel or fluid-containing cavity of a
patient, and having a connector means attached at a
proximal end of said catheter body for providing separate
30 connection to and fluid communication through each said
lumen, the improvement comprising:

a septum disposed within said catheter body and
running lengthwise therethrough, said septum being
offset from the longitudinal center axis of said
35 catheter body so as to define a first lumen having a
cross-sectional area sized to permit a selected
volumetric flow rate of fluid to occur therethrough by

1 means of gravity drainage, and so as to define a
second relatively smaller lumen having a cross-
sectional area sized to permit a substantially equal
volumetric flow rate of fluid to be returned through
5 said second lumen at a selected pressure.

7. An improved apparatus as defined in claim 6
wherein said septum is sealed to said catheter body at an
interior wall thereof near said distal end of the catheter
10 body, whereby said second lumen terminates at a point that
is longitudinally displaced from said distal end.

8. An improved apparatus as defined in claims 6 or
7 wherein said apparatus further comprises a first
15 plurality of longitudinally spaced openings formed on said
catheter body and through which said fluid enters into said
first lumen, and a second plurality of longitudinally
spaced openings formed on said catheter body essentially
diametrically opposite to said first plurality of openings
20 and through which return of said fluid from said second
lumen occurs, whereby fluid enters said catheter body on
one side thereof and is returned from said catheter body at
an essentially opposite side thereof so as to maximize
separation between fluid that is withdrawn from fluid that
25 is returned.

9. An improved apparatus as defined in claims 6 or
7 wherein said distal end of said catheter body is tapered,
rounded and comprises an opening which communicates with
30 said first lumen.

10. An extracorporeal oxygenation catheter apparatus
designed for simultaneous withdrawal of blood to be
oxygenated by means of gravity drainage and pressurized
35 return of blood that has been oxygenated, comprising:

1 an elongated catheter body having a distal end
and a proximal end, and comprising a septum disposed
within said catheter body and running lengthwise
therethrough, said septum being offset from the
5 longitudinal center axis of said catheter body so as
to define a first lumen having a cross-sectional area
sized to permit a sufficient volumetric flow rate of
said blood to occur in said first lumen as a result of
gravity drainage of blood therethrough, for purposes
10 of oxygenation and so as to define a second,
relatively smaller lumen having a cross-sectional area
sized to permit a substantially equal volumetric flow
rate of oxygenated blood to be returned under pressure
through said second lumen, said septum being sealed to
15 said catheter body at an interior wall thereof near
the distal end of said catheter body so that said
second lumen terminates at a point that is
longitudinally displaced from said distal end, and
said catheter body comprising a first plurality of
20 longitudinally spaced openings placed near said distal
end and through which said blood to be oxygenated
enters into said first lumen, and a second plurality
of longitudinally spaced openings formed on said
catheter body essentially diametrically opposite to said
25 first plurality of openings and through which return
of said oxygenated blood from said second lumen
occurs, whereby blood to be oxygenated enters said
catheter body on one side thereof and oxygenated blood
is returned from said catheter body at an essentially
30 opposite side thereof in order to maximize separation
between blood that is withdrawn from oxygenated blood
that is returned; and

 a connector joined to said proximal end of said
catheter body, said connector comprising a first
35 branch forming a first passageway for connection to
tubing through which said blood to be oxygenated is
withdrawn from said first lumen, and comprising a

1 second branch forming a second passageway for
connection to other tubing through which said
oxygenated blood is returned to said second lumen.

5 11. A method of extracorporeal blood oxygenation and
return of blood that has been oxygenated, comprising the
steps of:

10 withdrawing said blood to be oxygenated by
gravity drainage through a first lumen formed by a
septum in the interior of a catheter body and having
a first cross-sectional area sized so that a
sufficient volumetric flow rate for purposes of
oxygenation will occur by means of said gravity
15 drainage; and

20 returning said oxygenated blood under pressure
through a second lumen formed by said septum in the
interior of said catheter body adjacent to said first
lumen, said return of oxygenated blood occurring at a
volumetric flow rate that is substantially equal to
said selected volumetric flow rate through said first
lumen.

25 12. A method as defined in claim 11 wherein:
said withdrawing step comprises withdrawing said
blood to be oxygenated through a first plurality of
openings formed on said catheter body; and

30 said returning step comprises returning said
oxygenated blood through a second plurality of
openings formed on said catheter body essentially
diametrically opposite from said first plurality of
openings, whereby blood to be oxygenated enters said
catheter body on one side thereof and oxygenated blood
is returned from said catheter body at an essentially
35 opposite side thereof so as to maximize separation
between blood that is withdrawn from oxygenated blood
that is returned.

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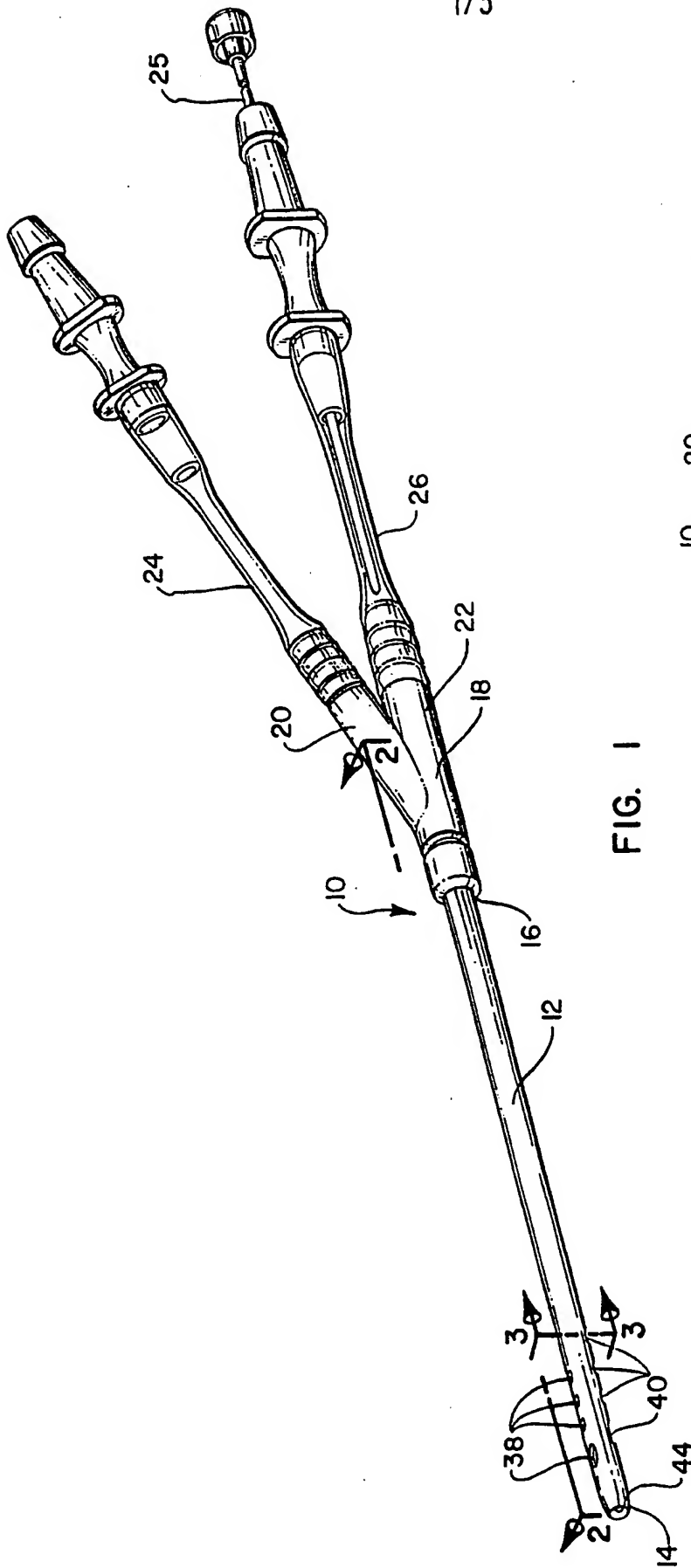


FIG. 1

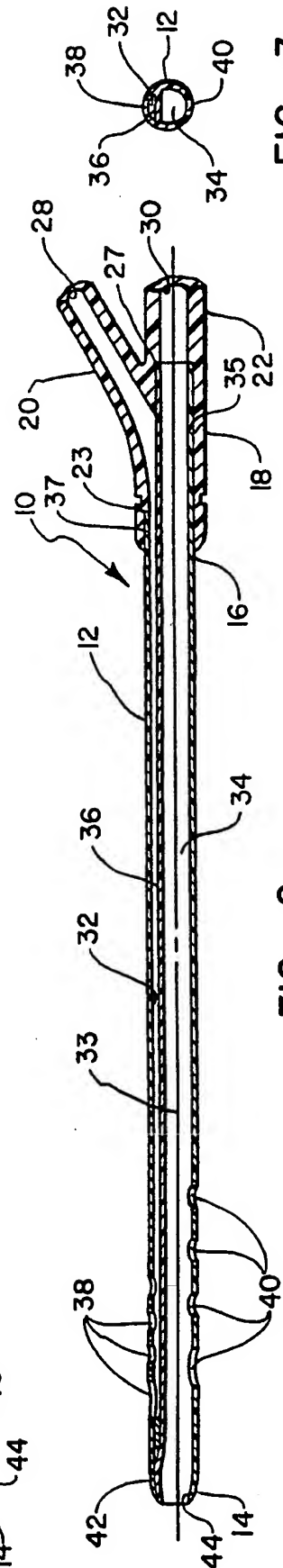


FIG. 2

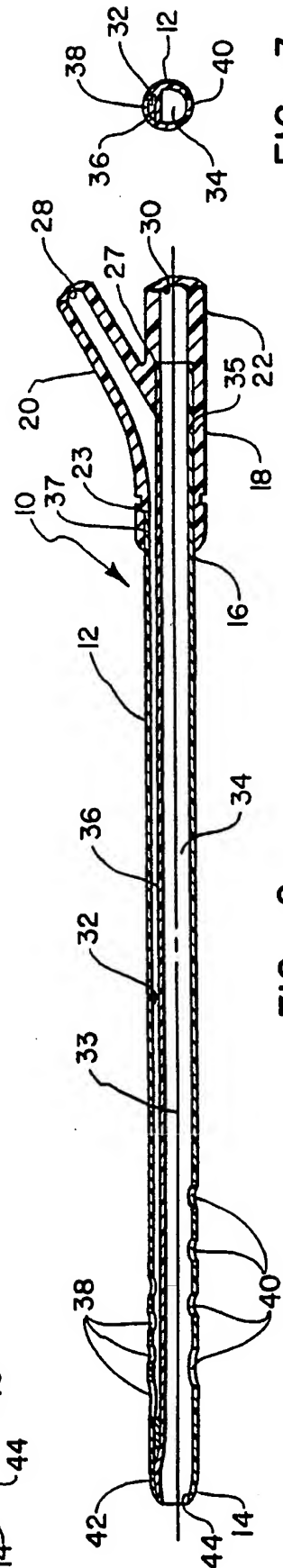


FIG. 3

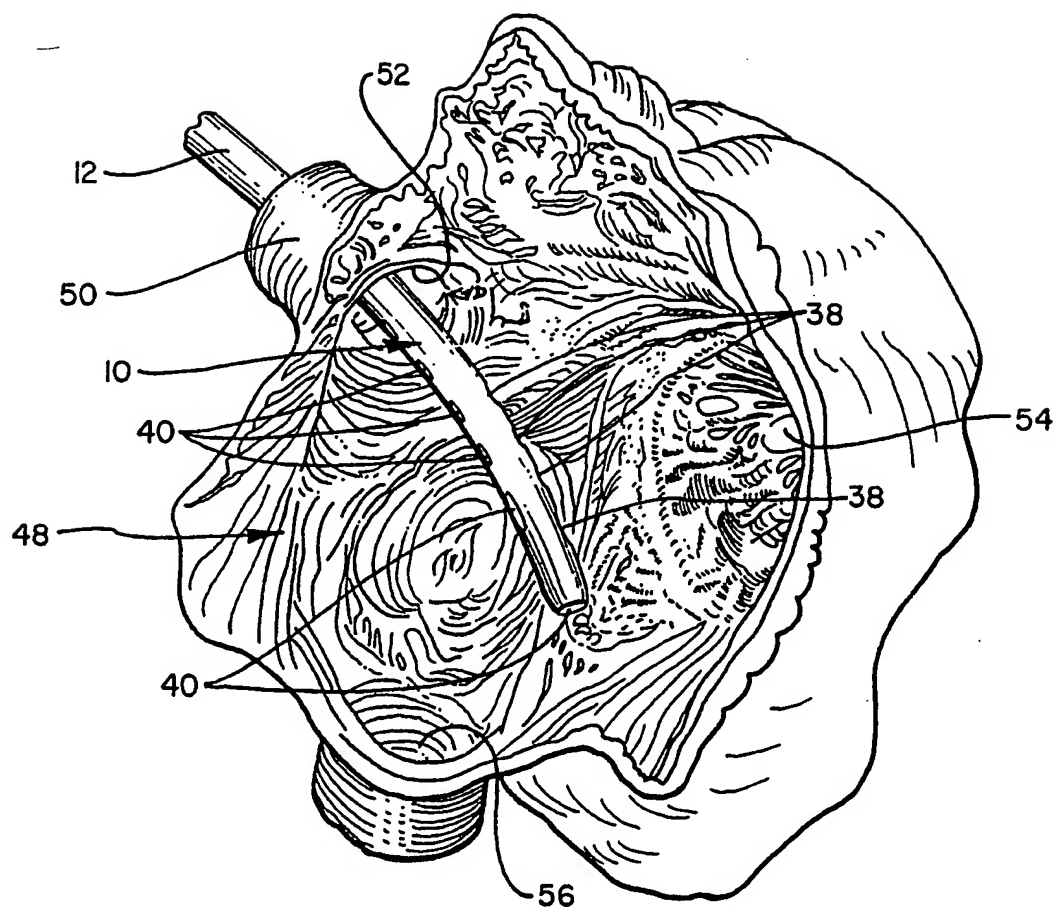


FIG. 4

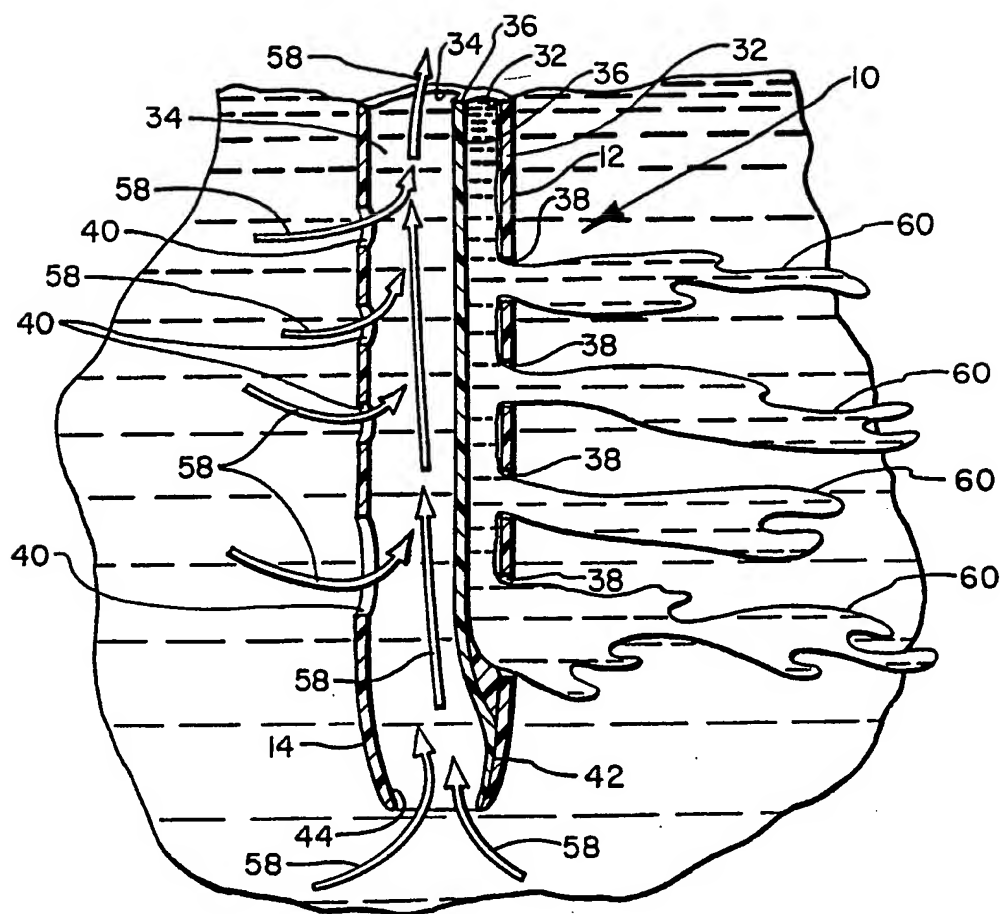


FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US90/06771

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ¹

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61M 5/00

US CL.: 604/43,280

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System |

Classification Symbols

US 604/27,43-45,264,280,4

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁶

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹³

Category ⁸	Citation of Document, ¹⁴ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁴
Y	US, A, 4,403,983 (EDELMAN et al.) 13 September 1983, see column 2, lines 25 - column 4, line 16.	5,9
Y	US, A, ,4451,252 (MARTIN) 29 May 1984 See figures 1-11, abstract.	1-3,5-7,9,11
Y	US, A, 4,583,968 (MAHURKAR) 22 April 1986 See figures 1-4, abstract.	1-3,5-7,9,11
X Y	US, A, 4,643,711 (BATES) 17 February 1987	1,2 3,5-7,9,11
Y	US, A, 4,753,640 (NICHOLS et al.) 28 June 1988 See figures 1-19 and abstract.	1-3,5-7,9,11

^{*} Special categories of cited documents: ¹⁵

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search ¹

04 APRIL 1991

International Searching Authority ¹

ISA/US

Date of Mailing of this International Search Report ¹

07 MAY 1991

Signature of Authorized Officer ¹⁶

RALPH LEWIS